Draft Policy Recommendations for Discussion and Decision
FACDQ Meeting #6

The Policy Work Group has worked diligently in the months since the July FACDQ meeting to develop this package of policy recommendations. This package is the result of a lot of give and take among members of the Policy Work Group. Though presented as separate issues, for purposes of FACDQ decision-making, the "package" as a whole should be kept in mind while viewing the individual parts.

The package of recommendations is a result of two concurrent Policy Work Group efforts: (1) to describe an approach that incorporates establishing nationally-promulgated limits and provides for laboratories to demonstrate their individual capabilities; and (2) to further develop the straw uses proposals discussed at the July FACDQ meeting.

The Policy Work Group developed recommendations related to the following policy issues:

1. Lab-Determined Detection Limits (DLs) and Quantitation Limits (QLs)
2. Method Promulgation
3. Demonstration of Laboratory Proficiency of Detection and Quantitation Limits
4. Future Updates of Promulgated Analytical Method DLs and QLs
5. Recommendations for NPDES Permits and Compliance Uses for WQBELS At or Below QL
6. Matrix Effects
7. Other Uses to Consider
8. Another Issue to Consider: Alternative Test Procedure
9. Implementation of the Final Committee Recommendations

Toward the end of the Policy Work Group's discussions of these policy issues, some members concluded that it would be helpful to think through a process for how their recommendations could be implemented. The Policy Work Group's laboratory caucus members developed a proposal for a framework for implementation for the committee's consideration. The basics of the laboratory caucus' proposed framework are presented in Attachment A.

Because the Policy Work Group did not discuss this framework for implementation extensively, the Group directed that it be an attachment to their recommendations. However, the Group liked the idea of presenting an example of such a process or framework. The Group encourages committee members to think about what they feel is important for an implementation process and bring their ideas to the December committee meeting to discuss.

DRAFT POLICY WORK GROUP RECOMMENDATIONS

1. Lab-Determined Detection Limits (DLs) and Quantitation Limits (QLs)[1]

Recommendation: The Policy Work Group recommends that the FACDQ develop and recommend promulgation of a descriptive process and procedure for individual laboratories to determine their actual detection and quantitation limits. The promulgated descriptive procedure should replace 40 CFR Part 136 Appendix B.

Discussion: It has been noted that clients or permittees have found it desirable to know and use the lowest possible detection limit a laboratory can achieve in circumstances such as engineering design studies. By the very nature of this situation, there is a need for a descriptive means to determine what a laboratory can achieve. This recommendation is very important to the laboratory community.

2. Method Promulgation

Recommendation: The Policy Work Group recommends to the FACDQ that when the EPA promulgates an analytical method in 40 CFR Part 136, detection limits (DLs) and quantitation limits (QLs) be included with the method. These limits will serve to define the minimum required performance of a laboratory, assist in comparing performance of one procedure to another (facilitating selection of a method most suitable for a given use), and define important thresholds for use in evaluating compliance. (See the section titled "NPDES Permits and Compliance Uses.") The limits will be published in a table in a promulgated rule in 40 CFR Part 136. [2]

Discussion: Although there has been considerable discussion of the special case of WQBELs that are below current analytical measurement capabilities (e.g., the "bad boys"), the recommendation to promulgate national DLs and QLs, while allowing for lab-specific demonstrations of limits lower than those set nationally, proposes that the same procedure/s would be used to determine DLs or QLs for situations where WQBELs are below analytical measurement capabilities.

Detection and quantitation limits will be established using a procedure recommended by the FACDQ for that purpose. The FACDQ still needs to develop a recommendation for how limits will be determined in the future. They will probably be determined by either a multi-laboratory or an inter-laboratory procedure that will be carried out by the method developer (e.g., EPA or a third party such as an instrument manufacturer). For example, if a multi-laboratory approach were recommended, individual laboratories would use the specified DL/QL procedure to determine their individual detection and quantitation limits. The method developer would then collect those data and perform the multi-lab calculation procedure for publication with the method.

[1] The Policy Work Group agreed to use the terms DL for detection limit and QL for quantitation limit.
[2] The PWG has agreed to incorporate a new table of promulgated detection and quantitation limits in a rule, but the Group has not had a full discussion of what would be included in the table.

The Policy Work Group recognizes that more work is needed on how to promulgate limits for existing methods where limits do not now exist and requests that the FACDQ provide direction to the Policy Work Group to further evaluate this issue. (See similar requests in recommendations section related to Future Updates and Implementation.)

3. Demonstration of Laboratory Proficiency of Detection and Quantitation Limits

Recommendation: The Policy Work Group recommends that the FACDQ develop a process for initial and on-going verification of DLs and QLs by laboratories.

Discussion: Future analytical methods developed by the Office of Water will include certain proficiency demonstrations of DLs and QLs by laboratories. Pending the outcome of decisions on uses, the FACDQ may decide that proficiency demonstrations will be required for DLs and/or QLs. All laboratories performing the method would be required to meet (or exceed) the promulgated detection or quantitation limit(s). In this sense, the promulgated DLs and QLs would be prescriptive.

If the FACDQ were to recommend a descriptive single laboratory procedure for demonstrating a laboratory's DL and QL, the procedure could be used to demonstrate that the laboratory's DL and QL meet the minimum prescriptive requirements of the promulgated method and to demonstrate the method's specific DL and QL for other uses. Two separate procedures could be used in this approach, but a single procedure would be much more efficient.

In some situations, it might be easier to demonstrate that one can achieve a prescribed detection limit than to demonstrate the lowest possible detection limit. This is largely because demonstrating the lowest possible limit requires much greater care and selection of spiking levels. However, it seems reasonable to assume that one could construct a procedure where the laboratory could perform either simplified spiking to demonstrate proficiency with the prescriptive DL and QL required or undertake the more onerous spiking required demonstrating its lowest possible DL and QL. Thus, the recommended procedure will not necessarily obligate the laboratory to adhere to the more costly spiking requirements, and the laboratory could use its client needs and other requirements to determine how much additional work and/or spiking would be appropriate.

EPA could use the results obtained by labs that choose to determine their lowest DL and QL as a resource in deciding if and when to update the promulgated DL and QL.

4. Future Updates of Promulgated Analytical Method DLs and QLs

Recommendation: The Policy Work Group suggests that the FACDQ recommend that EPA periodically review current capabilities of promulgated analytical methods. The focus of this review should be on methods where there have been significant improvements in detection or quantitation limits or on methods which do not contain DLs or QLs. This review would be particularly important for cases where detection and quantitation limits are critical to the permit program (e.g., those required for very low WQBELs). EPA

should focus on analytes for which current methods provide poor performance or do not meet program needs. EPA would not be obligated to update method detection or quantitation limits on an ongoing basis, regardless of current needs and/or available resources.

Discussion: EPA may elect to publish an Advance Notice of Proposed Rulemaking (ANPRM) in the Federal Register to seek public input on which methods should be considered for updating. EPA should assess the expected lower DL or QL and the use of those limits in Clean Water Act programs and determine if an update would be appropriate based on cost effectiveness or total program needs. For instance, EPA may note that a 20% improvement in the quantitation limit might be anticipated in an update but determine that the resources would be better spent in developing a method that would have a quantitation limit 20 times lower.

When EPA determines an update is appropriate, it should collect data from a variety of sources, including labs experienced in the particular analytical method. EPA would audit and/or validate the data by approaches it determines to be appropriate for the rulemaking and then, using the FACDQ-recommended procedure/s, determine new detection and quantitation limits. The FACDQ-recommended procedure should address the minimum number of laboratories to include in the update database.

If a third party were to compile the required data and submit it to EPA in a manner that EPA deemed adequately verifiable, EPA should use those data as the basis for an update. At the same time, such a submittal by a third party would not obligate EPA to go through rulemaking for a method update. EPA would still have the discretion to review the potential improvements versus its needs and costs to determine if an update would be cost effective.

Once EPA has compiled and audited or validated the necessary data and performed the DL/QL update procedure (e.g., the procedure(s) proposed by the FACDQ), it would update the DL/QL of the method(s) and/or, if a table is incorporated into 40 CFR Part 136, to update the values for selected method/analyte combinations through rulemaking.

5. Recommendations for NPDES Permits and Compliance Uses for WQBELs at or below QL:

Recommendation A:

1. Set average and daily maximum permit limits at the WQBEL. The permit shall also include a nationally-promulgated QL.
2. When determining average and daily maximum discharge levels, set values < QL equal to zero.[3]

[3] This footnote addresses recommendations 5A: 2, 3, and 5. A majority of the Policy Work Group preferred using zero for averaging. However, some PWG members preferred using some value for data greater than DL and less than QL for averaging when there is a detect between QL and DL. Additionally, a majority of the Policy Work

3. To determine compliance, compare discharge levels to the WQBEL after assigning 0 (zero)[4] to results < QL, as in #2 above.
4. A permittee must report to the regulator information less than QL and greater than or equal to DL. If the regulator requires reporting of this information as numeric values, the information shall be reported on a supplemental report. If the regulator requires reporting of this information as narrative text (for example, DNQ), the regulator may specify that it be reported directly on the DMR or on a supplemental report. The DL and QL must also be reported.
5. A regulator may[5] also include specific language in the permit that requires the permittee to take additional steps to assess information or mitigate for potential impacts when an effluent limitation is less than QL or detected values are less than QL. These steps may include analytical studies such as matrix studies, pollutant minimization programs, or other permit conditions outside of the determination of compliance with effluent limitations. Reports under such provisions will be done outside of the DMR reporting process, except that any additional effluent testing performed using approved analytical methods as part of the special studies must be reported according to the protocol in #4. When detected values below QL are not reported numerically, a regulator may require the permittee to submit numeric data with the permit application for use in determining reasonable potential.

Note 1: Both items 4 and 5 would require that the permittee obtain from the lab the estimated value for data ≥ DL and < QL. It would be the permitted entity's responsibility to maintain that data for a minimum period of 5 years during which time a permitting authority that requires only narrative text could request the numeric data.

Note 2: Dave Akers proposed an additional concept relating to recommendations 5.A.2. and 3; it is included as Attachment B.

Discussion: The QL referred to will be the promulgated quantitation limit derived from the most appropriate method,[6] taking into account sensitivity, selectivity, and matrix effects

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Group preferred using the term "may" rather than "shall" in recommendation #5. An alternative suggestion was to use zero for averaging coupled with "shall" for #5.

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[6] An alternative proposed approach would not specify an analytical method in the permit, just the numerical value of the nationally-promulgated QL. The permittee would be allowed to use any method to demonstrate it could meet the specified QL. This performance-based approach would require that the FACDQ specify what level of

("best" method) in 40 CFR Part 136. The FACDQ recommendation should make it clear that specification of the most appropriate method would apply only when pertaining to implementation of permit limits for WQBELs that challenge current analytical capabilities.[7] In this sense, the use of the promulgated QL is a prescriptive use and all NPDES permits will reference the promulgated QL.

Recommendation B: Current EPA guidance for implementing permit limits for WQBELs that challenge current analytical capabilities stipulates that the permit should specifically reference the most sensitive method approved in 40 CFR Part 136 and require its use to demonstrate compliance. The Policy Work Group recommends that the FACDQ modify this reference to "the most appropriate method, taking into account sensitivity, selectivity and matrix effects" (i.e., "best method") and that EPA then incorporate this revised guidance into the regulation that it issues to implement the FACDQ recommendations.

Discussion: To avoid a compliance situation where an update of 40 CFR Part 136 detection and quantitation limits results in lowering the QL such that values down to the new QL would be used for averaging instead of zero, the permit writer should be instructed to insert the numerical value of the most appropriate method for the given matrix at the time the permit is issued. These numerical compliance levels would be good for the term of the permit, unless the regulatory agency modifies the permit to make the change, perhaps along with a compliance schedule for meeting the new levels.

6. Matrix Effects

(Recommendation to be developed)

7. Other Uses to Consider

Recommendation: The Policy Work Group recommends that the FACDQ revisit its initial list of uses at the December FACDQ meeting and make a decision about whether or not to develop recommendations for additional uses. The list of additional uses for consideration includes the following:

- ambient monitoring 305(b)
- pretreatment
- non-regulatory operational monitoring
- stormwater monitoring
- other studies, such as fish tissues or biosolids characterization

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demonstration and/or validation would be required to substantiate the claim of equivalent quantification by any method other than the method used to define the level specified in the permit (e.g., the method described above as the most appropriate method).

[7] The PWG has had discussions about the "bad boys" and referred to a list of pollutants where WQBELs are below detection levels of the most appropriate method. For some substances, this will be permit-specific depending on the state, water quality criteria and procedures for translating criteria into effluent limitations.

8. **Another Issue to Consider: Alternative Test Procedures**

Recommendation: The Policy Work requests that the FACDQ decide if this issue is within the committee's charter and, if so, should the committee make it a priority to develop recommendations to EPA on updating the Alternative Test Procedures (ATP) program.

Discussion: Some members of the Policy Work Group expressed fundamental concerns with the scientific validity and the approval process of the ATP program. Others suggested there were ways to streamline the existing program. If the FACDQ chooses to make recommendations on this process a priority, its recommendations could include, but are not limited to, the following:

- Make methods approval a priority.
- Align priority of method approvals among the EPA Regions and the states.
- Provide clarity and certainty to EPA Regional Administrators as to their authority to approve interim methods at 40 CFR Part 136.4 and 136.5. Use the EPA Office of General Counsel (OGC) to provide clarification to EPA Regional Administrators on region-wide interim methods approval.
- Retain sufficient expert consultants or contractors on an "as needed" basis to review new methods and method modifications to minimize EPA resource requirements.
- Allow and encourage the proponent of a new or updated analytical method to draft the proposal and final rule promulgating the new or updated method.
- Un-bundle updates to the methods at 40 CFR Part 136.
- Include a severability clause in a proposal or final rule promulgating more than one new or updated analytical method.
- Propose updates to methods approved by voluntary consensus standards bodies (VCSBs) separately by VCSB and separate from other methods.
- Streamline the ATP promulgation process by promulgating a large number of individual rules (incremental rulemaking), as is done by EPA's Office of Air and Radiation (OAR).

9. Implementation of the FACDQ Recommendation

Recommendation: Initially, EPA would propose a new regulation which would essentially establish the recommendations of the FACDQ as regulations. This would include removing any current procedure (if that is the recommendation of the FACDQ), incorporating any recommended procedures, and making any other changes recommended by the FACDQ (e.g. new permitting regulations per our current discussion of uses).

Once those regulations are in place, the procedures would be utilized in all future EPA method development/validation work and DLs and QLs would be promulgated with all new methods. As deemed appropriate by EPA, additional Federal Register notices and rulemaking would be used to update the detection and quantitation limits.

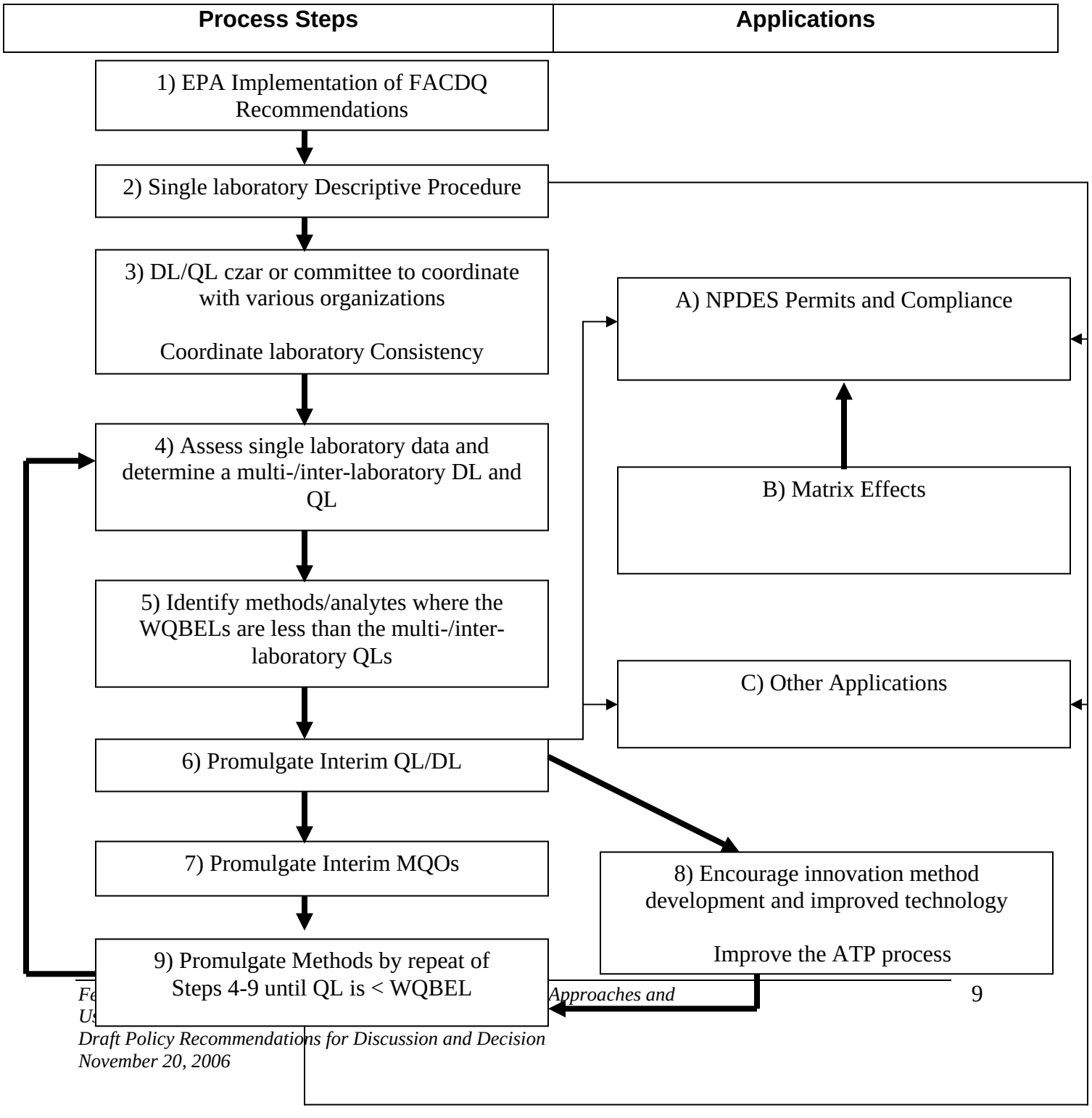
Discussion: A number of committee members have assumed that a prescriptive approach would entail setting, at the time of rulemaking, values for QL and DL for all methods in 40 CFR Part 136, or at least the most appropriate method for each pollutant. EPA has indicated this approach would be unmanageable. This proposal suggests that all future methods be promulgated with detection and quantitation limits and provide a means for those limits to be updated on an as-needed or appropriate basis. The latter could be used to develop DL and QL limits for current, approved Part 136 methods that lack such estimates.

There will inevitably be a gap in time between when EPA promulgates the new procedures and when the data necessary for the update process become available. Either EPA funds data generation or labs adopt the new procedures and develop the data that EPA might mine for a future update. Therefore, during the gap, states would have to find a way to set DLs and QLs for methods that do not list them for analytes that need them, perhaps using their current approach. Ideally, the states would adopt the nationally promulgated DLs and QLs as they become available in the future. At a minimum, the states' DLs and QLs would be equal to or more stringent than the nationally-promulgated DL and QL.

ATTACHMENT A

DRAFT FRAMEWORK FOR IMPLEMENTING FACDQ RECOMMENDATIONS

A framework or process that identifies a series of steps and interim measures to implement FACDQ policy recommendations is expected to facilitate decision-making by the FACDQ. One possible framework, the basics of which were developed by the laboratory caucus, is presented below. Key goals of this framework are to achieve QLs below WQBELS and to produce reliable data for decision-making.



The steps that follow are numbered to correspond to the steps in the framework on page 9.

PROCESS STEPS:

1. EPA implements the FACDQ recommendations through rulemaking.
2. Develop, promulgate, and implement a robust, scientifically valid procedure for single labs to measure their true limits for detection and quantitation.
3. Appoint a DL/QL czar or committee to coordinate with various organizations including permittees, EPA, states, environmental groups, ACIL, NELAC, INELA, and others to ensure that labs are actually using these limits as data censoring points when they report data. Currently labs are censoring data at various levels – sometimes DL, sometimes QL, and frequently at some arbitrarily assigned "reporting limit." Consequently, we really are unsure what laboratory capabilities are and what numbers for DL and QL should be promulgated.
4. Identify and implement the appropriate method for assessing single laboratory data to determine current laboratory capability by analyte (or method) and determine a multi-/inter-laboratory DL and QL according to the procedure(s) recommended by the FACDQ.
5. Identify methods/analytes where the WQBELs are less than the multi-/inter-laboratory QLs. A result of this step could be the prioritization of analytical methods for updating.
6. Promulgate interim minimum required laboratory performance for QL and DL for analytes/methods with WQBELs less than QL (i.e. "bad boys and girls").
7. Establish interim detection MQOs for false positive/negative and/or interim quantitation MQOs for accuracy/precision for the analytes identified in #6.
8. A national approach to setting detection and quantitation limits needs to include a process that encourages innovation in method development and improved technology. Improve the ATP process for problem analytes to encourage labs and instrument vendors to develop capabilities to achieve lower limits.
9. Promulgate Methods: Repeat steps 4-9 over time to achieve QLs that are below the WQBELS and develop more reliable data for decision-making related to the uses identified by the FACDQ.

APPLICATION OF THE PROCESS

The following are identified applications for which the above process would be used:

A. NPDES Permits and Compliance: Nationally promulgated Detection Limits (DL) and Quantitation Limits (QL) can be used to establish consistent compliance limits for permittees when appropriate steps are taken to assure that fair and correct limits are used.
B. Matrix Effects: Define the appropriate due diligence required by a permittee to demonstrate that a matrix effect renders the nationally-promulgated QL unachievable so that a variance to the promulgated limit can be granted more simply than happens now. This needs to be a reasonable process, not an academic exercise. The method with the lowest detection limit is not always the best method for every matrix. In fact, for samples that are not reagent water, selectivity is probably more important than sensitivity.
C. Other Applications: Are there other applications this process should be used for?

ATTACHMENT B

DAVE AKERS' ALTERNATIVE CONCEPT FOR NPDES AND COMPLIANCE USES FOR WQBELS AT OR BELOW QL

From Dave Akers Email (11/15/06):
A concern with the proposed approach for a prescriptive DL and QL has been raised in discussions amongst the state caucus members. The issue is, in setting a prescriptive QL that would be used for compliance determination, would we be "hamstringing" the development of new or improved analytical techniques (methods, equipment, etc.) that would allow the lab to detect and quantify the "bad boy and girl" pollutants at lower levels. This issue has also been raised by the lab caucus.

We realize that setting a prescriptive level for compliance determination would, theoretically, establish a level playing field. I say theoretically because states would still be free to establish lower QLs or to require the lab to quantify at their QL established using the FACDQ-recommended procedure. What we would like to open for discussion is the possibility of the FACDQ recommendation providing that a prescriptive QL be adopted as a ceiling for laboratory QLs, that labs would have to use the FACDQ-recommended procedure to establish their QL, that the permitted entity would be required to report at its lab's QL, and that the compliance enforcement threshold would be set at its lab's QL.

Instead of treating every value below the nationally promulgated prescriptive QL (NPPQL) as a zero for averaging, the permitted entity would use any value above the QL established by its lab but no greater than the nationally-promulgated prescriptive QL for averaging and values below the lab-established QL would be assigned a value of zero for averaging and reporting purposes.